REMARKS

Claims 10-17 are pending in the application. By action of this preliminary amendment, claims 10-12 have been amended. Claims 13 and 14 have been canceled. New claims 18-28 have been added. Reconsideration and allowance is respectfully requested in view of the remarks made below.

1. Amendments

Independent claims 10 and 12 have been amended in order to remove that material which has been objected to by the Examiner. The Applicant respectfully submits that the amendments made obviate the rejections made of record. The Applicant submits that these claims are in condition for allowance. Furthermore, newly amended claim 11, claims 15-17 and new claims 21, 25, 27 and 28 also obviate those issues raised in the previous office actions. As such, at least these claims are also in condition for allowance.

2. The Objection under 35 U.S.C. § 132(a)

In the February 9th Office Action an objection was made to the amendment of November 9, 2005. In particular, the material added in the paragraph beginning on page 2 at line 23 and ending on page 3 at line 2 was objected to for not being supported in the original disclosure. The Applicant respectfully submits that the material added to the specification is an inherent property of providing long term intravenous solutions to a human.

"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

The amendments to the specification relate to the usage of pH buffers in an intravenous solution. Maintaining the pH balance of a person's blood is imperative in order to maintain the life of the person. Anytime a prolonged administration of a neutral intravenous solution is given to a person it is necessary to provide a pH buffering agent in order to prevent the onset of those ailments associated with pH imbalance in the blood (acidosis or alkalosis).

Intravenous solutions which contain only non-acids or non-bases, e.g. sodium chloride, glucose, such as those disclosed in the Applicant's specification, usually have a pH slightly less than 7. In these non-buffer solutions this low pH represents a very small amount of acid. One has to add a fraction of a miliequivalent of strong base to a liter to make the solution alkaline. (Shires et al, 1948[1]; Garella et al, 1973[2]). In a solution having a net neutral pH (e.g. Saline or 5% glucose) one adds a pH buffer such as NaOH (or $NaHCO_3$) in order to achieve a pH of 7.4 (the average pH of blood). Therefore a neutral solution plus NaHC03 will on infusion cause no change in the pH of the blood (Gaudry et al., 1972[3]). One of ordinary skill in the art would recognize that the addition of a pH buffer in the Applicant's solution is necessary in order to avoid blood imbalance during the provision of intravenous solution over time.

Therefore the Applicant respectfully submits that the amendments to the specification do not constitute new matter since the material added is a known necessary part of the provision of long term intravenous solutions to a human in order to avoid complications caused by pH imbalance. Removal of the objection is respectfully requested.

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[1] SHIRES, G.T. and HOLMAN, J. "Dilutional Acidosis". Ann. Intern. Med. 28, 557; 1948. (Acidosis due to I.V. Fluids).

[2] GARELLA, S., DANA, C.L. and CHAZAN, J.A. "Severity of Metabolic Acidosis as a Determinant of Bicarbonate Requirements", N. Engl. J. Med. 289, 121; 1973.

[3] GAUDRY, P.L., DUFFY, C. and BOOKALLIL, M.J. "pH and Titratable Acidity of Intravenous Infusion Solutions". Anaesth. Intensive Care, 1, 41; 1972.

3. The Rejection under 35 U.S.C. §112, First Paragraph

Claims 10-17 stand rejected under 35 U.S.C. § 112, first paragraph as failing to meet the written description requirement. As noted above in section 1 of this paper, the amendments made to claims 10-12 obviate this rejection. Therefore at least independent claims 10 and 12 are in condition for allowance. Furthermore it is submitted that claims 11, 15-17, 21, 25, 27 and 28 are also in condition for allowance.

New claims 18-20, 22-24, and 26 are also in condition for allowance for the reasons provided above in section 2. The Applicant requests notice to that effect.

4. Conclusion

The Applicant has made an earnest effort to place this application in condition for allowance. If the Examiner feels that a telephone interview would expedite prosecution of this patent application, he is respectfully invited to telephone the undersigned.

Date: 4/9/06

By: _____

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